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09/739,940	12/19/2000	Stephen J. Fonash	823.0052USQ	4788

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EXAMINER

TRAN, MY CHAU T

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 02/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/739,940

Applicant(s)

FONASH ET AL.

Examiner

My-Chau T. Tran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,6,7,10-12,14-19,66,67,69 and 70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-3,6,7,10-12,14-19,66,67,69 and 70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

1. Applicant's amendment filed 12/2/02 in Paper No. 16 is acknowledged and entered. Claims 9, 20-65, 68, and 71-118 are canceled. Claims 1, 6, 7, 18-19, and 66 are amended. Claims 1-3, 6-7, 10-12, 14-19, 66-67, and 69-70 are pending.

Withdrawn Rejections

2. The previous rejections under 35 USC 112, first paragraph, for claims 1, 6-7, 9, and 18-20 have been withdrawn in view of applicant's amendment of claims 1, 6-7, 18-19, cancellation of claims 9 and 20, and amendment of the specification on page 28 between lines 14 and 15. The previous rejections under 35 USC 112, second paragraph, for claims 1-3, 6-7, 9-12, 14-21 and 66-70 have been withdrawn in view of applicant's amendment of claims 1 and 7, and cancellation of claim 20.
3. The previous rejections under 35 U.S.C. 102(b) for claims 1-2, 6-7, 10-12, 14-17 and 66, 68-70 as being anticipated by Köster (US Patent 5,605,798) have been withdrawn in view of applicant's amendments of claim 1 and argument.
4. The previous rejections under 35 U.S.C. 102(b) for claims 1-3, 6-7, 9-12, 14, 17-21 and 66, 69-70 as being anticipated by Apffel et al. (US Patent 5,705,813) have been withdrawn in view of applicant's amendments of claim 1 and argument.

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5. The previous rejections under 35 USC 103(a) as being obvious over Apffel et al. (US Patent 5,705,813) in view of Hancock et al. (US Patent 5,716,825) for claims 9 and 67-68 have been withdrawn in view of applicant's amendments of claim 1 and argument.

6. Claims 1-3, 6-7, 10-12, 14-19, 66-67, and 69-70 are treated on the merit in this Office Action.

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Maintained Rejections

8. Claim 66 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

9. Claim 66 recites that the type of substrate is silicon, semiconductors, insulators, organic materials, glasses, plastics, polymers, metals, or ceramics.

The specification discloses that type of substrate is glass, metal foil, plastics and silicon wafers (pg. 20 lines 5-6).

Nowhere in the specification is there a teaching that the type of substrate is insulators, organic materials, polymers, or ceramics.

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In the event that applicant believes support for the amendment is available in the specification. It is respectfully requested that applicant point to the page and line number where such support maybe found.

New Rejections – Necessitated by Amendment

Specification

10. The amendment filed 12/2/02 for page 7 (lines 9-19) is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material, which is not supported by the original disclosure, is as follows: the term “ceramic” was not originally disclosed as a type of substrate.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

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12. Claims 1-2, 10, 12, 14, and 69-70 are rejected under 35 U.S.C. 102(b) as being anticipated by Hutchens et al. (US Patent 5,719,060).

Hutchens et al. disclose a method and apparatus for affinity-directed detection of analytes, including desorption and ionization of analytes in which the analyte is not dispersed in a matrix solution or crystalline structure but is presented within, on or above an attached surface absorbing "matrix" material (thin film) (col. 4, lines 11-22). The method step comprise of exposing the derivatized surface of the substrate to a source of the analyte molecule so as to bind the analyte molecule to the surface and analyze the analyte by mass spectrometry (col. 16, lines 46-62). The analyte include biological macromolecules such as peptides and lipids (referring to claims 2 and 70) (col. 12, lines 4-11). The source of the analyte is liquid (referring to claim 69)(col. 35, lines 27-47). Therefore, the method and apparatus of Hutchens et al. anticipates the presently claimed invention.

13. Claims 1-3, 10, 12, 14, 17, 66, and 69-70 are rejected under 35 U.S.C. 102(e) as being anticipated by Nelson et al. (US Patent 5,955,729).

Nelson et al. teach a method for analyzing and identifying an analyte within a sample (col. 3, lines 41-63). The method step comprise of capturing the analyte by contacting the analyte with an interactive surface layer affixed to a conductive material and measuring the mass spectrum of the analyte by mass spectrometer (col. 12, lines 47-67). The conductive material includes metals (col. 3, lines 66-67). The analyte is in solution (col. 8, lines 19-21) and includes molecules such as proteins, lipids, and eukaryotic cells (col. 7, lines 22-32). The samples are delivered to the surface in regulated low volumes by a fully automated delivery flow systems

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(col. 8, lines 36-54). Therefore, the method of Nelson et al. anticipates the presently claimed invention.

14. Claims 1-2, 6-7, 10-12, 14, 17, 66, and 69-70 are rejected under 35 U.S.C. 102(e) as being anticipated by Siuzdak et al. (US Patent 6,288,390).

Siuzdak et al. teach a method for ionizing an analyte from light-absorbing semiconductors and the analyzing the ionized analyte (col. 4, lines 10-13). The method comprise of introducing a quantity of an analyte to a substrate to form an analyte-loaded substrate and analyzing the analyte by mass spectrometry (col. 4, lines 14-30; col. 7, lines 64-67 to col. 8, lines 1-8). The method step of loading the analyte onto a porous semiconductor substrate refer to as the analyte molecules being trapped or sorbed on the substrate (col. 8, lines 15-25). The semiconductor substrate includes semiconductors such as silicon and germanium (col. 8, lines 34-67 to col. 9, lines 1-10). The porous silicon substrate comprise of a crystalline silicon (substrate) (ref. # 22 of fig. 1(c)) and etched porous region that is modified chemically to improve control of the loading of the analyte (thin film) (ref. #20 and 26 of fig. 1(c)). The analyte of interest includes peptides, natural products, and small drug molecules (col. 19, lines 14-22). Therefore, the method of Siuzdak et al. anticipates the presently claimed invention.

Claim Rejections - 35 USC § 103

15. Claims 1-2, 6-7, 10-12, 14, 17-19, 66-67, and 69-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siuzdak et al. (US Patent 6,288,390) in view of Mian et al. (US Patent 6,319,469).

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Siuzdak et al. teach a method for ionizing an analyte from light-absorbing semiconductors and the analyzing the ionized analyte (col. 4, lines 10-13). The method comprise of introducing a quantity of an analyte to a substrate to form an analyte-loaded substrate and analyzing the analyte by mass spectrometry (col. 4, lines 14-30; col. 7, lines 64-67 to col. 8, lines 1-8). The method step of loading the analyte onto a porous semiconductor substrate refer to as "the analyte molecules being trapped or sorbed on the substrate (col. 8, lines 15-25). The semiconductor substrate includes semiconductors such as silicon and germanium (col. 8, lines 34-67 to col. 9, lines 1-10). The porous silicon substrate comprise of a crystalline silicon (substrate) (ref. # 22 of fig. 1(c)) and etched porous region that is modified chemically to improve control of the loading of the analyte (thin film) (ref. #20 and 26 of fig. 1(c)). The analyte of interest includes peptides, natural products, and small drug molecules (col. 19, lines 14-22).

The method of Siuzdak et al. does not expressly disclose that the sample is prepared by a separation means.

Mian et al. teach a device for performing microanalytical assays of biological, chemical, environmental, and industrial samples (col. 6, lines 24-27). The samples can be pre-concentrated and purified on the device by incorporating aqueous two-phase separation systems (col. 35, lines 9-23).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include that the sample is prepared by a separation means as taught by Mian et al. in the method of Siuzdak et al. One of ordinary skill in the art would have been motivated to include that the sample is prepared by a separation means in the method of Siuzdak

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et al. for the advantage of providing a pre-concentrated or purified sample. Since Mian et al. disclose that the device is useful for preparing samples for other analytical instruments such as mass spectrometry (col. 35, lines 1-8).

16. Claims 1, and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siuzdak et al. (US Patent 6,288,390) in view of Farmer et al. (*J. Mass Spectrom.*, **1998**, 3:697-704).

Siuzdak et al. teach a method for ionizing an analyte from light-absorbing semiconductors and the analyzing the ionized analyte (col. 4, lines 10-13). The method comprise of introducing a quantity of an analyte to a substrate to form an analyte-loaded substrate and analyzing the analyte by mass spectrometry (col. 4, lines 14-30; col. 7, lines 64-67 to col. 8, lines 1-8). The method step of loading the analyte onto a porous semiconductor substrate refer to as the analyte molecules being trapped or sorbed on the substrate (col. 8, lines 15-25). The semiconductor substrate includes semiconductors such as silicon and germanium (col. 8, lines 34-67 to col. 9, lines 1-10). The porous silicon substrate comprise of a crystalline silicon (substrate) (ref. # 22 of fig. 1(c)) and etched porous region that is modified chemically to improve control of the loading of the analyte (thin film) (ref. #20 and 26 of fig. 1(c)). The analyte of interest includes peptides, natural products, and small drug molecules (col. 19, lines 14-22).

The method of Siuzdak et al. does not expressly disclose that ammonium citrate is a signal enhancer.

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Farmer et al. teach a method of studying protein-protein and protein-ligand interactions by mass spectrometry (pg. 697, left col. 17-19). The mass spectrometry technique is MALDI mass spectrometry. The method comprise of dissolving both the matrix and the analytes in ammonium citrate, which provided an intense signal.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include ammonium citrate as a signal enhancer as taught by Farmer et al. in the method of Siuzdak et al. One of ordinary skill in the art would have been motivated to include ammonium citrate as a signal enhancer in the method of Siuzdak et al. for the advantage of providing a reagent that sequester ion such as salt that is generally found in bimolecular analysis because the salt would form adduct peaks in a mass spectrum that compete with the peaks of the molecular ion dividing and broadening the overall signal. Since Siuzdak et al. disclose that the existing MALDI mass spectrometer can be used to perform the analysis of the analyte-loaded porous semiconductor substrate (col. 13, lines 14-17). Therefore the method of Farmer et al. can be use in the method of Siuzdak et al.

Response to Arguments

17. Applicant's arguments with respect to claims 1-3, 6-7, 10-12, 14-19, 66-67, and 69-70 have been considered but are moot in view of the new ground(s) of rejection.

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Conclusion

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner is on ***Increased Flex Schedule*** and can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 703-306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

mct

February 20, 2003


PADMASHRI PONNALURI
PRIMARY EXAMINER